

<b>RUTH SMITH, Individually and as Widow</b>	)	
<b>for the Use and Benefit of Herself and the</b>	)	
<b>Next of Kin of RICHARD SMITH, Deceased,</b>	)	<b>Case #: 3:05-00444</b>
	)	<b>Judge Trauger</b>
<b>Plaintiff,</b>	)	
	)	
<b>-against-</b>	)	
	)	
<b>PFIZER INC., PARKE-DAVIS,</b>	)	
<b>a division of Warner-Lambert Company</b>	)	
<b>and Warner-Lambert Company LLC,</b>	)	
<b>WARNER-LAMBERT COMPANY,</b>	)	
<b>WARNER-LAMBERT COMPANY LLC and</b>	)	
<b>JOHN DOE(S) 1-10,</b>	)	
	)	
<b>Defendants.</b>	)	

Plaintiff Ruth Smith, as the Widow for the use and benefit of herself and the next of kin of Richard Smith, deceased, by and through her attorneys, hereby submits Plaintiff's Brief in Support of Dr. Cheryl Blume's Testimony and Plaintiff's Response to Defendants' Objections to the Proposed Statement of Plaintiff's Expert Dr. Cheryl Blume.

Brief in Support-Response to Blume Objections 5/13/2010 Page 1 of 25

Case 3:05-cv-00444 Document 244-9 Filed 05/13/10 Page 1 of 25 PageID #: 5364

Testimony	Objection	Response
¶ 2: “I have been asked to investigate and provide opinions about whether Warner Lambert and Pfizer failed to warn doctors and patient...”	<ul style="list-style-type: none"> <li>Any opinion that Defendants failed to warn “patients” is irrelevant, misleading and likely to confuse the jury under Tennessee’s learned intermediary doctrine. (FRE 402, 403)</li> </ul>	<p>FDA required warnings to be given to patients as part of the 2009 labeling change. These warnings also provide specific instructions to patients to monitor for changes in mood and behavior.</p> <p>The Court has already ruled on the admissibility of the patient package insert (ECF 199).</p> <p>See Plaintiff’s general comments to Defendants’ objections to Dr. Blume’s testimony.</p>
¶ 6: “It is also important for me to tell you that what I did here is the same tasks that I provide to drug companies outside of litigation. I used the very same methods as I have been using for the past 25 years.”	<ul style="list-style-type: none"> <li>Witness refused to disclose information concerning her work and “tasks” for drug companies outside of litigation. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on November 12, 2007 at pp. 22- 25.</li> </ul>	<p>Witness was under confidentiality agreements that did not allow her to divulge details as to whom she provided these services for.</p> <p>MDL Court already concluded that Dr. Blume was qualified to speak on the areas of her expertise.</p>
¶ 10: “It was approved to treat epilepsy and for the treatment of post-herpetic neuralgia --- a very limited type of nerve pain, also called “shingles”.”	<ul style="list-style-type: none"> <li>Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>Referring to post-herpetic neuralgia as a “very limited type of pain” is beyond the expertise of the witness and is misleading (FRE 403)</li> </ul>	<p>Dr. Blume, while not an M.D., has extensive knowledge of medical issues as a result of her training and experience. In her routine non-litigation activities, she reviews and opines upon the same sorts of information.</p> <p>Defendants’ own documents identify PHN as being a subset of neuropathic pain.</p>

Testimony	Objection	Response
¶ 12: “Also let me be clear: just because FDA has found the drug’s benefits outweighed the risk for uses like epilepsy and shingles pain, there is no proof that FDA ever decided the drug was safe for anything else.”	<ul style="list-style-type: none"> <li>• Lack of foundation. There is no reliable scientific evidence that safety has any relationship to the indication for use. (FRE 702)</li> </ul>	Dr. Blume's statements are a simple fact. There is no FDA document that says the drug is safe and or effective in populations other than those for which it was approved.
¶ 13: “Because the defendants were actually marketing and promoting Neurontin for unapproved, “off-label” uses far beyond these limited FDA approvals. Doing this placed the public at risk of being harmed, and Mr. Smith is the victim of the Defendants’ actions.”	<ul style="list-style-type: none"> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1)) Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Lack of foundation. There is no reliable scientific evidence that safety has any relationship to the indication for use. (FRE 702)</li> <li>• Improper and personal opinion characterizing Mr. Smith as “victim” of Defendants’ actions.</li> </ul>	<p>See Expert report of Dr. Blume ¶¶263-266. These opinions were disclosed.</p> <p>There is no FDA document that says the drug is safe and or effective in populations other than those for which it was approved.</p> <p>Defendant's own document, Plaintiffs' exhibit PX5392 sets forth the same opinion that different populations could have different risks.</p>

Testimony	Objection	Response
¶ 13: “Patients like Mr. Smith were not warned about the potential for suicide-related side effects with Neurontin.”	<ul style="list-style-type: none"> <li>Any opinion that Defendants failed to warn “patients” is irrelevant, misleading and likely to confuse the jury under Tennessee’s learned intermediary doctrine. (FRE 402, 403)</li> </ul>	<p>FDA required warnings to be given to patients as part of the 2009 labeling change. These warnings also provide specific instructions to patients to monitor for changes in mood and behavior.</p> <p>The Court has already ruled on the admissibility of the patient package insert (ECF 199).</p> <p>See Plaintiff’s general comments to Defendants’ objections to Dr. Blume’s testimony.</p>
¶ 14: “Based on my review of documents, Pfizer wasn’t careful and people like Mr. Smith died.”	<ul style="list-style-type: none"> <li>Improper personal opinion without any reliable scientific basis; improper characterization of Defendant’s conduct; not supported by any discernable regulatory requirement; unreliable; will not assist the trier of fact. (FRE 702)</li> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time. (FRE 403)</li> <li>Witness is not a specific causation expert.</li> </ul>	<p>Dr. Blume reviewed the adequacy of the company’s safety surveillance (pharmacovigilance) practices in light of the population using the drug. This is the exact non-litigation activities that Dr. Blume has been engaged in for more than 25 years.</p> <p>Defendant’s failure to conduct adequate pharmacovigilance is one of the principle bases for liability to Plaintiffs. Therefore, this statement is square on point.</p> <p>Defendants take Dr. Blume’s statement out of context when she provides the basis and reasoning behind her statement. Since she has rendered an opinion that the Defendant’s failure to conduct adequate safety monitoring with the general capacity of the drug to cause harm means that individuals have died.</p>

Testimony	Objection	Response
¶ 22: Even though the Defendants were fully aware that the drug could have these effects, the company marketed the drug “off label” to the very individuals who were most vulnerable. Yet this very critical safety information was withheld from doctors and patients.	<ul style="list-style-type: none"> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• There is no duty under Tennessee law for a pharmaceutical company to warn patients directly under the “learned intermediary doctrine.”</li> </ul>	<p>It is uncontested that the company was aware of the extent of the off-label use of Neurontin. Defendants' pled guilty to off label promotion of Neurontin. Defendants also pled guilty to the product having inadequate directions for use in off-label populations. Dr. Blume ties these facts together and what they meant in the context of regulatory responsibilities and the effect on the safety of patients.</p> <p>FDA required warnings to be given to patients as part of the 2009 labeling change. These warnings also provide specific instructions to patients to monitor for changes in mood and behavior.</p> <p>The Court has already ruled on the admissibility of the patient package insert (ECF 199).</p> <p>See Plaintiff's' general comments to Defendants' objections to Dr. Blume's testimony.</p>

Testimony	Objection	Response
<p>¶ 23: There are certain chemicals in the brain that effect how we feel. These are called neurotransmitters. You have already heard [<i>or will hear Plaintiff's expert</i>] Dr. Michael Trimble talk about these chemicals. When there is an increase or imbalance in these brain chemicals, people can get depressed and suicidal. Now the defendants knew that Neurontin affected these chemicals. This document <b>proves</b> Defendants admit that Neurontin affects neurotransmitters in the brain since the 1980s. This is a copy of Defendants' confidential research study from May 1984, which showed that Neurontin reduced the release of excitatory neurotransmitters like serotonin and norepinephrine. This is important because these effects could contribute to suicidal behavior. (bold supplied for emphasis by defense counsel) ¶ 25: Entire paragraph</p>	<ul style="list-style-type: none"> <li>• Dr. Blume concedes in her May 7, 2010 deposition that one or more specific mechanisms directly linking these drugs with the acts of self-injury or suicide-related behaviors have not been identified. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on May 7, 2010 at page 32. She further stated the causation mechanism is not "relevant" to a regulatory opinion.</li> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• Improper summary and comment on testimony without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> <li>• Duplicative to testimony of Dr. Michael Trimble. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on May 7, 2010 at pages 32 and 33 where witness testifies that other experts will testify concerning mechanisms of causation.</li> </ul>	<p>Dr. Blume ties Defendants' knowledge of Neurontin's mechanism of action into Defendants regulatory responsibilities. As such, it is reasonable for her to engage in a brief discussion of the relevance to these responsibilities. She is not providing substantive testimony on how Neurontin reduces neurotransmitters which is the testimony of Dr. Trimble.</p> <p>While it is true that causation is not required to enhance a label, Dr. Blume expresses opinions that when they company has relevant causation information, it should be shared with Doctors.</p> <p>Dr. Blume uses the referenced documents to establish notice that the company was aware of the mechanism of action of Neurontin. Furthermore, it is basic pharmacology, and Dr. Blume is a pharmacologist, that discusses the effects of neurotransmitters on the brain. Therefore, Dr. Blume is qualified to discuss neurotransmitters in this context. Understanding, from a regulatory and safety perspective how this information is important is exactly the tasks that Dr. Blume engages in her non-litigation activities.</p>

Testimony	Objection	Response
¶ 23: “For doctors treating vulnerable patients with psychiatric and pain conditions, this is critical information that was not in the label. Otherwise it was ‘don’t ask, don’t tell’ and business as usual.”	<ul style="list-style-type: none"> <li>• Improper personal testimony without scientific basis unsupported by any discernible regulatory requirement; unreliable; and will not assist the trier of fact.</li> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>	This is not personal testimony. Dr. Blume, as the author of hundreds of package inserts, is well aware of the importance of such information. She is providing this testimony in the context of the company sharing this information with doctors only if they ask for the information.
¶ 24: Entire paragraph	<ul style="list-style-type: none"> <li>• Rule of completeness (FRE 106)</li> <li>• Partial reference to deposition testimony, which should entitle defendant to play or read other parts of deposition</li> </ul>	Defendants have provided designations that can be played if and when the testimony of Dr. Tive is played.
¶ 26: “What this means is that 19 people who had no psychiatric problems before receiving Neurontin, later needed drug therapy for treatment of the depression triggered by Neurontin.”	<ul style="list-style-type: none"> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education regarding what triggers depression (FRE 702)</li> <li>• Outside scope of expert report. <i>See</i> ¶ 45 of Blume report.</li> </ul>	¶45 of Dr. Blume's report discusses this area extensively, so it had been disclosed. Furthermore, Dr. Blume is interpreting the very same information she interprets in her non-litigation activities.
¶ 27: “What this means is that the Neurontin in certain patients made their behavioral problems worse.”	<ul style="list-style-type: none"> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>	Dr. Blume is interpreting the very same information she interprets in her non-litigation activities. She is explaining to the jury the significance of the finding and what Defendants should have done in light of it.

Testimony	Objection	Response
¶ 28: “While the increase could be due to more people using the drug, it could also be due to the drug causing the effect in a vulnerable population, such as patients at increased risk for these events because of underlying diseases.”	<ul style="list-style-type: none"> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> <li>• Speculation</li> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>	<p>Dr. Blume is interpreting the very same information she interprets in her non-litigation activities.</p> <p>From a pharmacovigilance perspective, actions are taken precisely because of uncertainty. Dr. Blume's statement is not to show that Neurontin causes injury. It is to show that the data would have suggested uncertainty and should have been investigated by Defendants.</p>
¶ 29: “Most critical is that despite both of these charts, the labeling wasn't changed and off label use was skyrocketing.”	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Outside scope of expert report. <i>See</i> ¶¶ 168-172 of Blume report.</li> </ul>	<p>Dr. Blume is interpreting the very same information she interprets in her non-litigation activities.</p> <p>From a pharmacovigilance perspective, actions are taken precisely because of uncertainty. Dr. Blume's statement is not to show that Neurontin causes injury. It is to show that the data would have suggested uncertainty and should have been investigated by Defendants.</p> <p>Furthermore, the standards for changing the label are evidence of a reasonable association. Dr. Blume's opinion based upon her experience is that these two charts should have caused Defendants to take action and that Defendants failed to act appropriately.</p>

Testimony	Objection	Response
Exhibit 4147 (referenced in ¶ 36)	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802). Chart cited was prepared by plaintiff's counsel.</li> <li>• Hearsay within hearsay (FRE 802, 805)</li> <li>• Probative value substantially outweighed by danger of unfair prejudice (FRE 403)</li> <li>• Irrelevant (FRE 401, 402, 407)</li> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> </ul>	<p>FRE 703 allows an expert to rely upon inadmissible materials as long as they are of a nature routinely relied upon by experts in the field. Defendant themselves use the very same source of data and their experts cite to a similar report (Report of Dr. Alex Ruggieri 11/08/2008 page 10, Dr. Arrowsmith 11/08/2008 page 9)</p> <p>Data in question is that produced by Defendants to Plaintiffs from Defendants' own internal files and can be readily verified by Defendant.</p> <p>The data used is a summary under FRE 1006 of Defendants' own business records of a regularly conducted activity and are therefore a hearsay exception under 803(6). Furthermore, Plaintiffs use the data for notice to Defendants and not for the underlying truth of the individual reports. This court has already ruled on the use of aggregations of anecdotal adverse event reports (ECF 199).</p> <p>Dr. Blume opines that is important to look at specific adverse events in the context of all adverse events. The chart in question is similar to that which she creates in her routine, non-litigation activities when conducting pharmacovigilance.</p>

Testimony	Objection	Response
Exhibit 2061 (referenced in ¶ 37)	<ul style="list-style-type: none"> <li>Irrelevant (FRE 401, 402, 407)</li> <li>Subsequent remedial measures (FRE 407). Document Gabapentin Capture Aid was created in 2006.</li> </ul>	<p>Dr. Blume's discussion of the Gabapentin Data Capture aid serves to show that 1) the company could have engaged in a similar data collection before the death of Mr. Smith and 2) the company should have engaged in the collection before the death of Dr. Smith.</p> <p>Furthermore, Defendants experts criticize Dr. Blume for aggregating certain adverse event terms when Defendants themselves did the very same thing in its own routine activities.</p> <p>Also see Plaintiff's general response to Defendants' objections.</p>
¶ 37: Entire paragraph concerning Gabapentin Capture Aid	<ul style="list-style-type: none"> <li>Subsequent remedial measures (FRE 407). Document Gabapentin Capture Aid was created in 2006</li> </ul>	<p>Dr. Blume's discussion of the Gabapentin Data Capture aid serves to show that 1) the company could have engaged in a similar data collection before the death of Mr. Smith and 2) the company should have engaged in the collection before the death of Dr. Smith.</p> <p>Furthermore, Defendants experts criticize Dr. Blume for aggregating certain adverse event terms when Defendants themselves did the very same thing in its own routine activities.</p> <p>Also see Plaintiff's general response to Defendants' objections.</p>

Testimony	Objection	Response
¶ 37: “This shows that the company agrees that it was appropriate to combine the suicide related terms, just as I did a few moments ago.”	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Improper state of mind testimony</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>	Defendants place this issue front and center when they through their experts criticize Dr. Blume for aggregating suicide related terms. It is certainly fair for Dr. Blume to demonstrate the Defendants themselves engaged in the very same conduct in their routine course of business.

Testimony	Objection	Response
¶¶ 38-41: All paragraphs	<ul style="list-style-type: none"> <li>• Chart created by plaintiff's counsel. Witness concedes inability to recreate, test or validate work that created chart. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken November 12, 2007 at pp. 69, 97- 98, 102-103</li> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> </ul>	<p>This Court has already ruled on this very issue with respect to Dr. King and cited an opinion involving the very same kind of data with the very same expert and the very same individual preparing the data for the expert.</p> <p>Furthermore, the parties entered into a stipulation acknowledging that both parties had separate, but equal access to the data in question and that it was agreed that data extracted using the same parameters by either party would yield equal results.</p> <p>Defendants have failed to provide any evidence that such charts are inaccurate in any way despite having the ability to readily do so.</p> <p>Furthermore, Defendants themselves in the routine course of business created substantially similar charts as discussed by Dr. Blume in her ¶42</p> <p>Please see Plaintiffs' general response to Defendants' objections.</p>

Testimony	Objection	Response
Exhibit 4159 (Referenced in ¶¶ 43-45)	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802). Chart cited was prepared by plaintiff's counsel.</li> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1)) Probative value substantially outweighed by danger of unfair prejudice (FRE 403)</li> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> </ul>	<p>This Court has already ruled on this very issue with respect to Dr. King and cited an opinion involving the very same kind of data with the very same expert and the very same individual preparing the data for the expert.</p> <p>Furthermore, the parties entered into a stipulation acknowledging that both parties had separate, but equal access to the data in question and that it was agreed that data extracted using the same parameters by either party would yield equal results.</p> <p>Defendants have failed to provide any evidence that such charts are inaccurate in any way despite having the ability to readily do so.</p> <p>Furthermore, Defendants themselves in the routine course of business created substantially similar charts as discussed by Dr. Blume in her ¶42</p> <p>Please see Plaintiffs' general response to Defendants' objections.</p>

Testimony	Objection	Response
<p>¶ 42: “Unfortunately for Mr. Smith, the company only did this because FDA required the company to review the information. This chart was created at a time that the company was already aware that the FDA had concluded that Neurontin and other drugs increased the risk of suicidal behavior.”</p>	<ul style="list-style-type: none"> <li>Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>	<p>This chart was in fact created in June 2008 after the FDA alert and statistical review had been published. At no time before had the company prepare such a chart. Dr. Blume opines that her chart, as well as this chart prepared by Defendant demonstrate a signal prior to the death of Mr. Smith. Dr. Blume states that the evidence shows that the company did not review the suicide question at all before the FDA required them to look at this issue starting in April 2004.</p>

Testimony	Objection	Response
¶¶ 43-45: All paragraphs	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802). Chart cited was prepared by plaintiff's counsel.</li> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> <li>• Any opinion that Defendants failed to warn "patients" is irrelevant, misleading and likely to confuse the jury under Tennessee's learned intermediary doctrine. (FRE 402, 403)</li> </ul>	<p>This Court has already ruled on this very issue with respect to Dr. King and cited an opinion involving the very same kind of data with the very same expert and the very same individual preparing the data for the expert.</p> <p>Furthermore, the parties entered into a stipulation acknowledging that both parties had separate, but equal access to the data in question and that it was agreed that data extracted using the same parameters by either party would yield equal results.</p> <p>Defendants have failed to provide any evidence that such charts are inaccurate in any way despite having the ability to readily do so.</p> <p>Furthermore, Defendants themselves in the routine course of business created substantially similar charts as discussed by Dr. Blume in her ¶42</p> <p>Please see Plaintiffs' general response to Defendants' objections.</p>

Testimony	Objection	Response
<p>¶ 46: Now, Defendants may say the words “suicidal” or “suicide gesture” were included in the premarketing labeling events for Neurontin, but this was only in their laundry list of side effects. This was simply not good enough in terms of adequately providing doctors and patients with directions to use Neurontin safely, particularly in light of the postmarketing evidence I have shown you today.</p>	<ul style="list-style-type: none"> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• Witness is not a physician and should not be permitted to opine what is “good enough for physicians.”</li> <li>• Misstates duty of pharmaceutical company to warn patients directly.</li> </ul>	<p>Dr. Blume has been responsible for the writing of hundreds of labels and negotiating the language of these labels with the FDA. As such, her more than 25 years experience engaging in this very activity qualifies her under rule 702.</p> <p>Her opinion is grounded upon her exhaustive review of the post-marketing data in the possession of the company. Furthermore, Defendants' own expert, Dr. Arrowsmith, opined that she found the term suicide gesture to be inadequate:</p> <p>Arrowsmith-Lowe, Janet 1/8/2009 page 139 Q. Okay. What does the term suicide gesture mean? A. I think that is an archaic term in my opinion that underestimates the -- the potential lethality of people who attempt suicide. I don't -- in my opinion a suicide gesture is really a suicide attempt.</p> <p>Furthermore, the FDA required warnings to be given to patients as part of the 2009 labeling change. These warnings also provide specific instructions to patients to monitor for changes in mood and behavior.</p> <p>The Court has already ruled on the admissibility of the patient package insert (ECF 199).</p> <p>See Plaintiffs' general comments to Defendants' objections to Dr. Blume's</p>

Testimony	Objection	Response
¶ 47: Entire paragraph	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> <li>• Witness is not a physician and should not be permitted to opine what is “good enough for physicians.”</li> <li>• Misstates duty of pharmaceutical company to warn patients directly.</li> </ul>	<p>See Plaintiffs' motion <i>in limine</i> (ECF 82) for Dr. Blume's basis.</p> <p>Prior to December, 2005, the company report completed suicide events as unlabeled events.</p> <p>This testimony is clearly within Dr. Blume's expertise as a regulatory and pharmacovigilance expert. She is opining on whether the labeling and the actions of the company demonstrate that completed suicide was not in the label.</p> <p>The paragraph does not reference warnings to patients.</p>

Testimony	Objection	Response
¶ 48: “So, don’t believe the defendants if they claim that they ever warned for “suicide” during Mr. Smith’s life.”	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> </ul>	<p>See Plaintiffs' motion <i>in limine</i> (ECF 82) for Dr. Blume's basis.</p> <p>Prior to December, 2005, the company report completed suicide events as unlabeled events.</p> <p>This testimony is clearly within Dr. Blume's expertise as a regulatory and pharmacovigilance expert. She is opining on whether the labeling and the actions of the company demonstrate that completed suicide was not in the label.</p> <p>The opinion was previously disclosed. See Blume Report ¶233, ¶277, ¶¶287-288. It was also extensively discussed in her November, 2007 deposition.</p>
Exhibit 2001 (Referenced in ¶ 50)	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802) Hearsay within hearsay (FRE 802, 805)</li> <li>• Probative value substantially outweighed by danger of unfair prejudice (FRE 403) Irrelevant (FRE 401, 402, 407)</li> </ul>	This objection has been overruled by the Court (ECF 199)

Testimony	Objection	Response
¶¶ 50-51: Entire paragraphs	<ul style="list-style-type: none"> <li>Any opinion that Defendants failed to warn “patients” is irrelevant, misleading and likely to confuse the jury under Tennessee’s learned intermediary doctrine. (FRE 402, 403)</li> <li>Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>	<p>FDA required warnings to be given to patients as part of the 2009 labeling change. These warnings also provide specific instructions to patients to monitor for changes in mood and behavior.</p> <p>The Court has already ruled on the admissibility of the patient package insert (ECF 199).</p> <p>See Plaintiff’s general comments to Defendants’ objections to Dr. Blume’s testimony.</p> <p>Dr. Blume has established the foundation for her opinion using either Defendants own documents or documents known to the Defendants. She sets forth the standard for changing the label and how Defendants’ knowledge was adequate to make such a change.</p> <p>Furthermore, she rebuts arguments from Defendants’ experts that suggest the company could not have known of the need to change the label before the January, 2008 FDA alert.</p>

Testimony	Objection	Response
¶ 54: Entire paragraph.	<ul style="list-style-type: none"> <li>• Outside scope of expert report.</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>	<p>These documents are dated after Dr. Blume's expert report, but were exchanged with Defendants by Rule 26 disclosure on August 13, 2008</p> <p>Furthermore, additional documents were recently produced by Defendants in early 2010 and for which Dr. Blume also supplemented her disclosure in March 28, 2010 and April 16, 2010.</p>
¶ 55: "This is a document from 1999 that predates Pfizer purchasing Warner-Lambert. In contrast to the defense noted above, Christopher Wohlberg describes Neurontin as the 'snake oil of the 20th century'."	<ul style="list-style-type: none"> <li>• Incomplete quotation; rule of completeness (FRE 106)</li> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> </ul>	<p>This is a direct quote from the document. Defendants pled guilty for off-label promotion for uses such as discussed in the document. This document shows what a high ranking employee of Pfizer thought of the drug before Pfizer owned it.</p> <p>Dr. Blume sets for the duplicitous statements by the company. It also can be seen by the jury as evidence of reckless conduct that Pfizer thought the drug was "snake oil", suggesting lack of efficacy, yet failed to properly investigate the safety in those populations.</p>

Testimony	Objection	Response
Exhibit 5809 (Referenced in ¶¶ 57-59)	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Irrelevant (FRE 401, 402, 407)</li> <li>• Not proper subject for expert testimony</li> </ul>	<p>Defendants' experts claim that the company did not conclude that Neurontin (and other drugs) increase the risk of suicidal behavior. Document is a record of a regularly conducted activity of the company and expresses Defendants' understanding of the FDA's position on whether the drugs cause an increase in the risk of suicide.</p> <p>The Court has already ruled (ECF 199) that post incident materials are admissible.</p>
¶ 57: Entire paragraph	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Irrelevant as 2009 discussions with FDA as to content of class label for AEDs does not bear on any issue of liability or damages in this case (FRE 401, 402, 407)</li> </ul>	<p>Defendants' experts claim that the company did not conclude that Neurontin (and other drugs) increase the risk of suicidal behavior. Document is a record of a regularly conducted activity of the company and expresses Defendants' understanding of the FDA's position on whether the drugs cause an increase in the risk of suicide.</p> <p>The Court has already ruled (ECF 199) that post incident materials are admissible.</p>
¶ 59: "However, other authors who are not hired by Defendants ..."	<ul style="list-style-type: none"> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>	<p>It is fact true that the authors of the two papers did not write those papers after being retained by Defendants as litigation experts. In contrast, Dr. Gibbons' entire work in the area of anticonvulsants did not begin until after he was retained by Defendants in this case.</p>

Testimony	Objection	Response
¶ 61: “These authors (at page 1406) found that ‘the risk of attempted or completed suicide was meaningfully increased for gabapentin. They do indicate that there is ‘no clear understanding of a mechanism of action that could lead to suicidal behavior,’ but then they go ahead and say that Gabapentin has been ‘associated with behavioral problems such as aggression and hyperactivity...’”	<ul style="list-style-type: none"> <li>• Incomplete quotation; rule of completeness (FRE 106)</li> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• Witness could not answer questions in deposition about whether aggression and hostility include suicide or suicide attempts. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on May 7, 2010 at page 42, lines 5-13.</li> </ul>	<p>Defendants are free to cross examine on the completeness.</p> <p>Dr. Blume regularly reviews the scientific and medical literature as part of her non-litigation activities. The materials in question are of a nature that individuals in her field regularly review. The MDL Court has already found Dr. Blume to opine on such materials.</p> <p>Defendants pull Dr. Blume's statements out of context and misrepresent the facts. Dr. Blume was unwilling to comment upon the references cited by the authors of the JAMA paper without seeing the references contemporaneously</p>

Testimony	Objection	Response
¶ 62: Entire paragraph	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Any opinion that Defendants failed to warn “patients” is irrelevant, misleading and likely to confuse the jury under Tennessee’s learned intermediary doctrine. (FRE 402, 403)</li> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>	<p>Dr. Blume properly sums up her opinions that she has rendered throughout her entire statements. Dr. Blume has already been found by the MDL Court competent to render her opinions.</p> <p>FDA required warnings to be given to patients as part of the 2009 labeling change. These warnings also provide specific instructions to patients to monitor for changes in mood and behavior.</p> <p>The Court has already ruled on the admissibility of the patient package insert (ECF 199).</p> <p>See Plaintiff's' general comments to Defendants' objections to Dr. Blume's testimony.</p>

Dated: May 13, 2010

Respectfully submitted,

THE LANIER LAW FIRM, P.L.L.C.

By: /s/ W. Mark Lanier  
W. Mark Lanier, Esq.  
Dara G. Hegar, Esq.  
Ken S. Soh, Esq.  
Maura Kolb, Esq.  
Robert Leone, Esq.  
126 East 56th Street, 6th Floor  
New York, NY 10022

- and -

FINKELSTEIN & PARTNERS, LLP

By: /s/ Andrew G. Finkelstein

Andrew G. Finkelstein, Esq.  
Kenneth B. Fromson, Esq.  
1279 Route 300, P.O. Box 1111  
Newburgh, NY 12551

- and -

BARRETT & ASSOCIATES, P.A.

By: /s/ **Charles F. Barrett**  
Charles F. Barrett, Esq.  
BPR # 020627  
6518 Highway 100, Suite 210  
Nashville, TN 37205

*Attorneys for Plaintiff Ruth Smith*

**CERTIFICATE OF SERVICE**

I hereby certify that on this the 13th day of May, 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

Aubrey B. Harwell, Jr., Esq.  
W. David Bridgers, Esq.  
Gerald D. Neenan, Esq.  
Robert A. Peal, Esq.  
Neal & Harwell, PLC  
2000 One Nashville Place  
150 Fourth Avenue, North  
Nashville, TN 37219

Prince C. Chambliss, Jr., Esq.  
Evans & Petree, PC  
1000 Ridgeway Loop Road, Suite 200  
Memphis, TN 38120

Mark S. Cheffo, Esq.  
Catherine B. Stevens, Esq.  
Skadden, Arps, Slate, Meagher & Flom LLP  
Four Times Square  
New York, NY 10036

Andrew Howell Myers, Esq.  
James Ernest Hooper, Esq.  
Stephen Ernest Oertle, Esq.  
Wheeler Trigg O'Donnell LLP  
1801 California Street, Suite 3600  
Denver, CO 80202-2617

Faith E. Gay, Esq.  
Quinn, Emanuel, Urquhart, Oliver & Hedges, LLP  
51 Madison Avenue, 22<sup>nd</sup> Floor  
New York, NY 10010

**/s/ Andrew G. Finkelstein**

Andrew G. Finkelstein